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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
PATTON, AMANDA K

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,426	REGHABI ET AL.	
	Examiner	Art Unit	
	Amanda Patton	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-24-9*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment dated July 22, 2009 is acknowledged. Currently claims 1-68 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 12, 26, 42, 49-52, 54-60, and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Heil Jr. et al. (USPN 6,304,786). Heil discloses the claimed method including: implanting an implantable sensor at a single site in a patient, (e.g. Figures 1-2), wherein the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements (e.g. tip electrode 400 and ring electrodes 310A-C capable of sensing a variety of different heart electrical signal parameters including heart rate, QRS duration, and AV delay) and wherein the implantable sensing elements are operable though electrical communication with an external controller (e.g. implantable pulse generator 110 is external to the lead)via a respective interconnect of a plurality of interconnects, each of the interconnects independently connect to a respective on of the implantable sensing elements (e.g. plurality of conductors 304A-D as shown in Figure 4A and 4B); each sensing element capable of sensing a respective

physiological parameter (e.g. each electrodes 400 and 310A-C is capable of sensing different hear electrical signal parameters which will be different for each electrode as they are located in slightly different locations and are quantifiable values; Col. 4, lines 34-61), reading an output from at least one implantable sensing element from a single site that is a quantifiable value (e.g. all electrical signal parameters that are measured are quantifiable values), evaluating the patient based on the output, and administering therapy based on the output (e.g. Col. 1, line 58 - Col. 2, line 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-25 and 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil. Heil discloses the claimed invention but does not disclose expressly administering therapy/evaluating the patient comprises administering therapy/evaluating the patient for myocardial infarction, myocardial ischemia, angina, adjusting a function or placement of an implantable cardiovascular defibrillator disposed within the patient, sepsis, septic shock, a patient receiving extracorporeal membrane oxygenation, a patient undergoing cardiac bypass, a patient during dialysis; and classifying a severity of a condition of a patient based on an output read from at least one implantable sensing element; and a patient is in a surgical and an intensive care environment; and implanting an implantable sensor at a single site in a triage patient and in

a patient in the field. It would have been an obvious matter of engineering design choice to a person of ordinary skill in the art to modify the implantable sensing elements to administer/evaluate therapy to a patient as taught by Heil, to include those parameters listed in the claimed limitations above, because Applicant does not disclose that these limitations provide an advantage or solves a stated problem over and above the like/similar claimed limitations listed in the 35 U.S.C. 102(e) rejection over Heil above. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the claimed limitations as taught by Heil, because each sensor of Heil is capable of sensing a physiological parameter with the data sensed by each sensor being convertible to an appropriate form and transferable through conductors to perform a desired medical function as needed for the benefit of the patient. Therefore, it would have been an obvious matter of design choice to modify the invention of Heil to obtain the invention as specified in the claims listed above.

In the alternative, for the above mentioned therapy, environment, and location of a patient, it is well known in the art for sensing elements to respond to lactate, blood oxygen saturation, blood pressure, etc., and to administer therapy for myocardial infarction, myocardial ischemia, angina, etc., and for patients to be in surgery, triage, etc. for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Heil to include the claimed limitations above for providing the method with the predictable results of a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings.

Claims 4-11, 27-33, 43-48, 53, and 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil in view of Gord et al. (USPN 5,999,848, as previously cited).

Regarding **claims 4, 8, 9, 11, 30-31, 33,** Heil discloses the claimed invention except an implantable sensor that wherein reading/evaluating a patient based on an output from at least one of an implantable sensing elements comprises reading an output from an implantable sensing element that responds to glucose, temperature, or pH. Gord discloses an implantable sensor wherein reading/evaluating a patient based on an output from at least one of an implantable sensing elements comprises reading an output from an implantable sensing element that responds to glucose (e.g. Col. 7, lines 30–33 and 45–48), temperature (e.g. Col. 7, lines 30–34), or pH (e.g. Col. 7, lines 30–33). It would have been obvious to replace the cardiac metric sensors of Heil with the sensors of Gord in order to provide the system with the ability to sense a variety of parameters for providing the system the predictable results of assuring accuracy and reliability of the data gather (e.g Gord, Col. 7, lines 39-41).

Regarding **claims 5-7, 10, 27-29, 32, 43-48, 53, and 61**, Heil and Gord disclose the claimed invention but does not disclose expressly reading/evaluating a patient based on an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to lactate, blood oxygen saturation, blood pressure, and potassium. It would have been an obvious matter of engineering design choice to a person of ordinary skill in the art to modify the implantable sensing elements to sense/evaluate the biological and physiological parameters as taught by Heil and Gord, to include those parameters listed in the claimed limitations above, because Applicant does not disclose that these limitations

provide an advantage or solves a stated problem over and above the like/similar claimed limitations listed in the rejection over Heil and Gord above. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the claimed limitations as taught by Heil and Gord, because each of these sensors are configured to sense different parameters e.g., multiple, sensors to be employed within the device, with the data sensed by each sensor being convertible to an appropriate form and transferable through conductors to perform a desired medical function as needed for the benefit of the patient. Therefore, it would have been an obvious matter of design choice to modify the invention of Heil and Gord to obtain the invention as specified in the claims listed above.

In the alternative, for the above mentioned sensing elements, it is well known in the art for sensing elements to respond to lactate, blood oxygen saturation, blood pressure, etc. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Heil and Gord to include the claimed limitations above for the purpose of providing the method with the predictable results a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings.

Regarding **claims 62-64**, Heil discloses the claimed invention except a device wherein each implantable sensing element comprises a respective power supply, wherein the respective power supply of each of the implantable sensing elements is for powering the implantable ensuing element. Gord discloses that it was known in the art to including sensing elements wherein each implantable sensor comprises a respective power supply (e.g. capacitor 40 that supplies power to integrated circuit 38 for controlling the sensor; Fig. 3A; Col. 7, lines 58-65). It would have been obvious to one having ordinary skill in the at the time the invention was made

to include the individual power supplies of Gord in the device of Heil in order to provide the system with a sensor capable of working independently of the other sensors for providing the predictable results of a more reliable sensor configuration.

Claims 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil in view of Mcivor (USPGPUB 2002/0023852). Heil discloses the claimed invention except a housing having an aperture for allowing fluid to pass into a volume inside the housing to sense a biological parameter, a physiological, or an analyte. Mcivor discloses that it was well known in the art at the time the invention was made to include an aperture for allowing fluid to pass to sense a parameter (e.g. open slot 46 of Figure 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the aperture of Mcivor in the device of Heil since such a modification would provide the device with the predictable results of the ability to easily and accurately sense a parameter.

Response to Arguments

Applicant's arguments with respect to claims 1-68 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762